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(71) Applicant(s)
Gar Investment Corporation

(Incorporated in USA - California)

Suite 221, 19528 Ventura Boulevard, Tarzana, California 91356, United States of America

(72) Inventor(s)
Roger Lewis

(74) Agent and/or Address for Service
Ablett & Stebbing
45 Lancaster Mews, Lancaster Gate, LONDON, W2 3QQ, United Kingdom

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GB 2274996 A WO 89/07468 A1 WO 88/02250 A1
WO 87/05793 A1 US 5354258 A US 5230334 A
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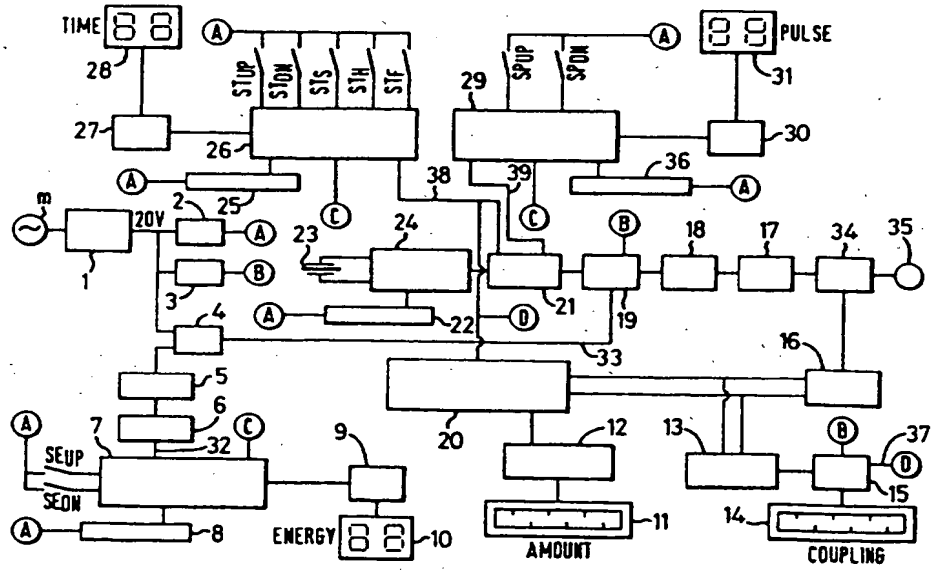
(54) Ultrasound apparatus for non invasive cellulite reduction

(57) The apparatus comprises an ultrasound generator with driving means 4 connected to an output synthesizer 24, output amplifiers 18,19 and pulse control means 29. The output synthesizer 24 produces vibrations at a predetermined frequency and the output amplifier 18 controls the magnitude of vibrations supplied via an output terminal 35 to an applicator head (not shown). Output signals and pulse control means are preferably controlled by microprocessors 7, 29. The device allows the ultrasonic treatment of cellulite at a predetermined frequency of about 3.3 MHZ and at a predetermined depth of about 1.27-2.54 cm from the skin surface. The pulse control means 29 modulates the predetermined frequency in an on/off fashion and thereby limits unnecessary heating of the skin or subcutaneous tissue during treatment.



At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1995

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NON-INVASIVE CELLULITE REDUCTION APPARATUS

The present invention relates to a non-invasive cellulite reduction apparatus.

In the human body, the musculature is overlaid by an outer layer comprising subcutaneous tissue and then the dermis and epidermis, the latter being the surface of the human body colloquially identifiable as the skin.

In certain regions of the body, particularly the tummy, upper legs and buttocks of the female human body,there is a tendency for a thickening of this outer layer. Furthermore, the thickened layers tend to have a different texture when compared with other adjacent regions of skin which are not thickened. Indeed, a rather lumpy appearance can sometimes be visually discernable. It has also been noted that these thickened regions tend to have a lower skin temperature. Consequently, it will be apparent that the effects of the thickening are physically and visually detrimental.

Various dietary and exercise methods have been proposed in an attempt to reduce the thickened regions. However, it has been found that they often do not respond well to even rigorous dietary and exercise methods and in addition it is difficult to target such dietary and exercise methods to the specific regions of the body. Indeed, it has been noted that people with little other bodily fat still retain these thickened regions.

Research has now established that the thickened regions arise from a fat, known as cellulite, which can build up in the subcutaneous tissue. It is believed that when fat occurs in the human body, it can build up as cellulite in a cell. However, the cell wall tends to become calcified as a result of incorrect diet in which case it is not then possible for the cellulite to effectively pass out through the calcified cell wall notwithstanding rigorous conditions of diet and exercise.

Thus, to counter the detrimental effects of cellulite, various known invasive techniques have been developed for

Furthermore, it has been found that the effectiveness of cellulite reduction is proportional to the square of the power transferred into the tissue. Thus, by controlling the energy level, the effective reduction in cellulite can be significantly altered thereby allowing targeted and selective reduction of cellulite according to the region effected and the degree to which it is effected by cellulite.

Preferably, said predetermined frequency is manually settable.

By having the frequency manually settable, it is possible to target the depth of penetration into the human surface thereby controlling where the ultrasound vibrations interact. This enables controlled reduction of the cellulite.

In a preferred embodiment of the invention the predetermined frequency has a value of 3.3 MHZ ± 0.5 MHZ.

By having such a value, the apparatus is automatically set to a preferred frequency for general operation whilst retaining flexibility of operation. The lower the frequency, the deeper the penetration and the higher the frequency the more the actual human surface is heated.

Conveniently, said major portion comprises 50% and said predetermined depth falls with 1.27 to 2.54 cm of said surface.

It has been found that an optimum reduction of cellulite occurs by having 50% of the ultrasound energy transferred to the tissue within a depth of the human surface between 1.27 to 2.54 cm. This optimises the reduction of the cellulite because the ultrasound penetrates the tissue at the human surface to a prescribed depth such that most of the energy is transferred to the tissue at that depth rather than being transferred to deeper tissue. Generally, the ultrasound has a frequency tolerance of ± .08 MHZ.

In one embodiment, the driving means comprises an oscillator means and an amplifier means; wherein the energy level control means alters the power output of the amplifier means to alter the level of driving of the ultrasound generator.

Thus, a particular length of time for the cellulite reduction can be set thereby freeing the operator of the apparatus to concentrate on the contact of the applicator means with the human surface.

Conveniently, said predetermined time interval in manually settable.

By having the predetermined time manually settable, it is possible to provide the operator of the apparatus with control and flexibility over the way in which the ultrasonic energy is transferred to tissues according to differing amounts of cellulite present.

It is preferred that the apparatus further comprises means for calculating the amount of transfer of ultrasound vibrations between said human surface in contact with said surface of the applicator means.

By monitoring the coupling between the applicator means and the human surface, it is possible for the operator to know how effective the transfer of ultrasound energy is to the tissue thereby enabling them to alter other variables if necessary to compensate for coupling changes.

It is also preferred that the apparatus further comprises means for calculating the total amount of ultrasonic vibrations transferred to said human surface.

As a result, it is possible to keep records of the amounts of ultrasonic energy transferred to the tissues to aid in evaluating the future requirements to reduce the cellulite.

According to another aspect of the present invention there is provided a non-invasive cellulite reduction apparatus comprising:-

an ultrasound generator for generating ultrasound vibrations;

an applicator means capable of being vibrated by the ultrasound generator for transferring ultrasound vibrations to a human surface in contact with a surface of the applicator means;

means for driving the ultrasound generator at a predetermined frequency whereby a major portion of said

through logic gating 21 to a power amplifier driver 19 powered by 12 volts from terminal B. The output of the power amplifier driver 19 is then supplied to an amplifier means in the form of a MOSFET power amplifier 18 which has an output magnitude controlled by the level of output signal appearing on the line 33. The magnitude of the output from the amplifier 18 controls the level of the ultrasonic energy available at the applicator head.

The output from the power amplifier 18 is passed through a 3.5 MHZ band pass filter 17 to a load impedance measuring circuit 34 before appearing as an output signal at an output terminal 35. The applicator head contains an ultrasonic generator in the form of a crystal which is connected to be oscillated by the output signal appearing at the terminal 35. It will be apparent that other forms of ultrasonic generation can be employed.

The level of the output signal appearing on line 33 controls the level of the ultrasound energy available at the applicator head. The signal on the line 33 is derived from an energy level control means in the form of a microprocessor 7 which is connected to a voltage to current converter 6 by a line 32 and then to the regulator 4 via a square root extractor 5. In this way, the voltage appearing on the line 32 is converted into a current and the square root of the magnitude of that current is supplied as a control signal to the regulator 4 to control the level of the output signal from the regulator 4 on line 33 and hence the level of the ultrasonic energy available at the applicator head.

A series of switches 8 supplied with 5 volts from terminal A are connected to the microprocessor 7 so as to provide a default setting for the level of the output signal from the regulator 4. However, a switch SE_{UP} and a switch SE_{DN} are provided for increasing or decreasing the voltage on line 32 so as to increase or decrease the level of the output signal of the regulator 4 and hence to increase or decrease the level of the ultrasonic energy available at the applicator head. The microprocessor 7 also provides a signal to a driver

provides a simple, efficient and effective way of controlling the manner by which a predetermined amount of ultrasonic energy can be transferred to the tissues containing cellulite so as to optimise the beneficial effects of the reduction of cellulite by ultrasound.

It has been found that the time interval of application of ultrasound is important to the reduction in cellulite. Accordingly, a timing control means in the form of a microprocessor 26 is connected to the logic gating 21 via a line 37. In this way, when the appropriate gate value appears on line 37, the frequency output from the synthesizer 24 is passed to the power amplifier 19, subject to gating according to the gate value on line 36, and when the appropriate gate value does not appear on line 37, the frequency output from the synthesizer 24 is not passed to the power amplifier 19.

The gate value on line 37 is set to appear for a predetermined time according to a time setting once a start switch ST_S has been actuated. A series of switches 25 are connected to the microprocessor 26 so as to provide a default time setting. However, a switch ST_{UP} and a switch ST_{DN} are provided for increasing or decreasing the default time setting. In this way, it is possible to control the length of time for which ultrasonic energy is applied to the skin and hence the dose of ultrasound energy applied to the skin. A further switch ST_F is connected to the microprocessor 26 for actively finishing or stopping the production of ultrasound energy and another switch ST_H is connected to the microprocessor 26 for temporarily halting or holding the production of ultrasound energy.

The microprocessor 26 also provides a signal to a driver 27 so as to drive a display 28 to display the available time remaining for application of the ultrasonic energy to the skin and also provides a 4 MHZ clock output signal to a terminal output C .

It can be seen therefore that the present invention provides a simple, efficient and effective way of controlling

duty cycle. A maximum of 3 watts cm^{-2} is typically set by health and safety requirements. However, it should be noted that if the energy level is doubled, it has been found that the effects of cellulite are quadrupled due to a square law relationship between energy level and effectiveness.

Then, the operator sets the pulse rate by means of the switches SP_{UP} and SP_{DN}. Typically, a 50 Hz pulse rate is set with a pulse width ratio or duty cycle of 50% ± 20%.

Then, the operator sets a time for application of the ultrasound by means of the switches ST_{UP} and ST_{DN}. Typically, treatment times are increased linearly in time per treatment up to approximately 20 minutes. However, after 40 minutes, it has been found that treatment time becomes less effective.

It should be noted that research by the applicant has shown that it is important to use the correct amount of ultrasound energy for a particular human surface with results being proportional with the square of the power transferred into the tissue containing cellulite. In this respect, it is noted that it has been found that the average power is not the deciding factor, but the peak power delivered to the cellulite containing tissue. For example, if the pulse width ratio is 50%, effectively halving the average power, the treatment results decrease only approximately 20% compared with applying un-modulated ultrasound energy.

Thus, the energy level, pulse rate and time values are set and displayed on the respective displays. The operator then applies a suitable ultrasound transfer gel to the cellulite region to be treated and presses the applicator head to that region. Switch ST_S is then actuated and the application of ultrasound to the cellulite containing tissue starts. Immediately, the coupling of the ultrasound energy to the region is determined and displayed on display 14. At the same time, a cumulative amount of ultrasound energy is displayed on display 11. At the end of the time period set, the apparatus automatically stops generation of ultrasound energy and the total amount of ultrasound energy can be readily recorded from the display 11. A sound or light means

ultrasound application has been used. In this way, a predetermined amount of time of ultrasound energy production can be purchased.

It will be understood that the embodiment illustrated shows an application of the invention in one form only for the purposes of illustration. In practice, the invention may be applied to many different configurations, the detailed embodiments being straightforward for those skilled in the art to implement. For example, whilst the present invention shows various components as separate, it would be possible to arrange the components in a more integral form.

an ON/OFF frequency of 50 Hz.

9. Apparatus according to any one of claims 6 to 8 wherein the pulse control means modulates the predetermined frequency in an ON/OFF fashion with a pulse width ratio of 50 % ± 20%.

10. Apparatus according to any preceding claim further comprising switching means for disconnecting said driving means from said ultrasound generator.

11. Apparatus according to any preceding claim further comprising timing means for controlling the drive means to drive the ultrasound generator for a predetermined time interval.

12. Apparatus according to claim 11 wherein said predetermined time interval in manually settable.

13. Apparatus according to any preceding claim further comprising means for calculating the amount of transfer of ultrasound vibrations between said human surface in contact with said surface of the applicator means.

14. Apparatus according to any preceding claim further comprising means for calculating the total amount of ultrasonic vibrations transferred to said human surface.

15. A non-invasive cellulite reduction apparatus comprising:-

an ultrasound generator for generating ultrasound vibrations;

an applicator means capable of being vibrated by the ultrasound generator for transferring ultrasound vibrations to a human surface in contact with a surface of the applicator means;

means for driving the ultrasound generator at a predetermined frequency whereby a major portion of said transferred ultrasound vibrations are absorbed within a predetermined depth of said human surface; and

a pulse control means for controlling the drive means to modulate the predetermined frequency in an ON/OFF fashion.

16. Apparatus according to claim 15 wherein the

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Claims searched: 1-14; 19 (in part) **Date of search:** 14 October 1996

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Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.O): A5R (REKA, REKX)

Int Cl (Ed.6): A61B 19/00; A61H 23/00, 23/02; A61N 7/00, 7/02

Other: ONLINE: WPI, CLAIMS, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X	GB 2274996	(YOUNG M J R et. al.) page 5 lines 12-14; page 7 lines 5-8; Claim 6	1-4
A	WO 89/07468 A1	(FELLNER D G) page 1 lines 4-8; page 9 lines 4-16	1-4
X	WO 88/02250 A1	(DYNAWAVE CORP.) page 7 lines 13-22; page 8 lines 28-32; page 9 lines 8-17	1-4, 6,7 & 9
X	WO 87/05793 A1	(COOPER LASERSONICS) page 4 line 21-page 5 line 6; page 8 lines 3-7; page 9 lines 3-10; page 10 lines 3-15; page 14 lines 23-29	1-4
X	US 5354258	(DORY J) column 1 line 54-column 2 line 10; column 6 lines 15-29 & 47-52; column 7 lines 48-66; column 8 lines 20-29	1-4
X	US 5230334	(KLOPOTEK P J) column 2 lines 27-38; column 3 lines 60-64; column 4 lines 41-53	1-4
X	US 4938217	(LELE P P) column 4 lines 15-16; column 5 lines 15-31; Claim 1	1-4

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.